# **EXHIBIT A**

## STATE SETTLEMENT AGREEMENT AND RELEASE

## I. THE PARTIES

#### II. PREAMBLE

- A. WHEREAS, TAP is entering into a civil settlement agreement with the United States of America, acting through and/or on behalf of its Department of Justice and the United States Attorney's Office for the District of Massachusetts, and the Office of Inspector General of the United States Department of Health and Human Services ("HHS-OIG"); TRICARE Management Activity ("TMA")(formerly known as the Office of the Civilian Health and Medical Program of the Uniformed Services), a field activity of the Office of the Secretary of Defense, the United States Department of Defense, and relators in certain federal False Claims Act lawsuits, as well as settlement agreements with the state of New York and numerous other states, all of which are intended to resolve civil claims for the conduct alleged in Paragraph F below;
- B. WHEREAS, this Agreement addresses the state of New York's claims against TAP for the conduct alleged in Preamble Paragraph F below;

- C. WHEREAS, on or before October 16, 2001, or such other date as the Court may set in United States of America v. TAP Pharmaceutical Products Inc., Criminal Action No. [to be assigned] (District of Massachusetts) (the "Criminal Action"), or such other date as may be determined by the Court, TAP has agreed to enter a plea of guilty pursuant to Fed. R. Crim. P. 11(e)(1)(C) to a one count Information alleging a violation of Title 18, United States Code, Section 371, namely, a conspiracy to violate the Prescription Drug Marketing Act, 21 U.S.C. § 331(t) and 333(b) by causing the billing of free drug samples;
- D. WHEREAS, at all relevant times, TAP marketed and sold the drugs Lupron® and Lupron Depot® (collectively "Lupron") in various dosages to physicians, health maintenance organizations, hospitals, wholesalers, distributors and others for use in treatment of prostate cancer;
- E. WHEREAS, the state of New York contends that TAP caused to be submitted claims for payment for Lupron to the state's Medical Assistance Program ("Medicaid") established pursuant to Title XIX of the Social Security Act;
- F. WHEREAS, the state of New York contends that it has Medicaid-related civil claims against TAP under various statutes and the common law for engaging in the following alleged conduct from January 1991 through the present, involving the marketing, sale and pricing of Lupron for treatment of prostate cancer:
- (i) The state of New York contends that TAP, through certain of its employees, provided, and conspired to provide, free samples of the drug Lupron to certain providers (including physicians), knowing and expecting that those providers would prescribe, distribute and/or administer the free drug samples to patients and that those free samples would

be illegally billed to the Medicaid program. The state of New York further contends that the purpose of providing these free drug samples varied, but that among those purposes were: permitting Medicaid providers to obtain money from the reimbursement for the samples of Lupron; inducing Medicaid providers to order Lupron; providing a source of money for Medicaid providers to pay past-due balances owed to TAP; and increasing the income of Medicaid providers.

- (ii) The state of New York contends that TAP knowingly and willfully offered and/or paid illegal remuneration to certain providers, physicians, physician practices, health maintenance organizations and others in various forms, including, for example, grants, free Lupron, debt forgiveness, travel and entertainment, consulting and audit services, administration fees, nominally priced drug, and VCRs and TVs, for the purpose of either unlawfully obtaining orders to purchase the drug Lupron from TAP or causing Lupron to be placed on formulary by a provider, which drug TAP knew was paid for by the Medicaid program.
- (iii) The state of New York contends that TAP knowingly and willfully offered and/or paid illegal remuneration to providers by marketing TAP's "Return-to-Practice" program to providers to induce unlawful orders to purchase the drug Lupron for treatment of prostate cancer, which drug TAP knew was paid for by the Medicaid program. The state of New York further contends that TAP's Return-to-Practice program consisted of inflating the Average Wholesale Price ("AWP") used by Medicaid for reimbursement of the drug Lupron, deeply discounting the price paid by providers to TAP for the drug ("the discounted price"), and marketing the spread between the AWP and the discounted price to providers as additional profit to be returned to the providers from Medicaid reimbursements for Lupron. The state of New

York further contends that TAP concealed the discounted price from Medicaid and other governmental agencies by omitting material information about providers' actual cost, by falsely advising providers that the discounted price could not and should not be reported to Medicaid, and by auditing providers to ensure the claims for payment were submitted at the inflated AWP rather than the discounted price paid by the provider. The state of New York also contends that as a consequence of this conduct, its Medicaid program was damaged.

- (iv) The state of New York contends that TAP manipulated reported prices, including AWP, to increase reimbursement from the Medicaid program. Specifically, the state of New York contends that TAP engaged in a marketing scheme where it set AWPs of Lupron at levels far higher than the majority of its customers actually paid for the drug when purchasing either directly from TAP or through a wholesaler or distributor. As a result, the state of New York contends that TAP's customers received reimbursement from the Medicaid program at levels significantly higher than the providers' actual costs or the wholesalers' average price. The state of New York further contends that certain providers submitted claims for payment to the Medicaid programs that were subsequently paid, based upon falsely inflated AWPs, to the financial detriment of the Medicaid program;
- (v) The state of New York contends that TAP knowingly misreported and underpaid its Medicaid rebates for Lupron used for treatment of prostate cancer, *i.e.*, the amounts that it owed to the state under the federal Medicaid Rebate Program, 42 U.S.C. § 1396r-8. The state of New York further contends that TAP was generally required on a quarterly basis to rebate to its state Medicaid program the difference between the Average Manufacturer Price ("AMP") and its "Best Price," as defined by 42 U.S.C. § 1396r-8(k)(1) and 1396r-8(c)(1)(C).

The state of New York alleges that TAP falsely reported to the Center for Medicare and Medicaid Services ("CMS") (formerly the "Health Care Financing Administration" or "HCFA") its Best Price for Lupron used for treatment of prostate cancer because TAP calculated its Best Prices for Lupron without accounting for "off-invoice" price concessions provided in various forms, including, for example, grants, free Lupron, debt forgiveness, travel and entertainment, consulting and audit services, administration fees, nominally priced drugs, and VCRs and TVs. As a result, the state of New York contends that TAP misreported and underpaid its Medicaid rebates to the states under the Medicaid Rebate Program.

TAP's conduct alleged in Preamble Paragraph F is hereinafter referred to as the "Covered Conduct."

- G. WHEREAS, the state of New York contends that it has administrative claims against TAP for administrative and monetary penalties under state and federal law for the Covered Conduct.
- H. WHEREAS, other than such admissions as TAP makes in connection with its guilty plea in the Criminal Action, TAP denies the remaining allegations of the state of New York set forth herein.
- I. WHEREAS, to avoid the delay, expense, inconvenience and uncertainty of protracted litigation of these claims, the Parties mutually desire to reach a full and final compromise of the civil and administrative Medicaid-related claims the state of New York has against TAP.

#### III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

- 1. TAP agrees to pay to the United States, to the individual states, to the relators in certain federal False Claims Act lawsuits and to any relators in any pending state court *qui tam* or "whistleblower" lawsuits, collectively, the maximum collective sum of five hundred eighty five million dollars (\$585,000,000) (the "Settlement Amount"). Payments to the United States and to the individual states shall be made pursuant to the following terms and conditions:
- A. TAP has agreed to pay to the United States the sum of five hundred fifty nine million four hundred eighty three thousand five hundred sixty dollars (\$559,483,560) (the "Federal Settlement Amount"), which represents the federal share of the Settlement Amount and the share of the Settlement Amount payable to the relators in certain federal False Claims Act lawsuits. The Federal Settlement Amount shall be paid pursuant to the civil settlement agreement entered between TAP and the United States (the "Federal Agreement").
- B. TAP agrees to deposit into an escrow account the sum of twenty five million, five hundred sixteen thousand, four hundred forty dollars (\$25,516,440) (the "State Settlement Amount"), which represents the state-funded portions of the claims settled for the Medicaid programs of all fifty states and the District of Columbia ("the Participating States"). TAP shall pay the State Settlement Amount into an escrow account within seven business days after the latest date on which all of the following have occurred: (1) the Federal Agreement is fully

the custody and control of a Medicaid Fraud Control Unit, which shall be designated by the negotiating team for the National Association of Medicaid Fraud Control Units and which shall act as Escrow Agent and shall retain such funds until their release in accordance with the payment terms set forth in subparagraph E below.

- C. The total portion of the Settlement Amount paid by TAP in settlement for alleged injury to the Medicaid Program for the state of New York is \$9,802,253.39, consisting of a portion paid to the state of New York under this Agreement and another portion paid to the federal government as part of the Federal Settlement Amount. The individual portion of the State Settlement Amount allocable to the state of New York, and which may be withdrawn by the state of New York from escrow pursuant to this Agreement, is \$5,055,088.32 (the "Individual State Settlement Amount"), plus any accrued interest on that portion of the State Settlement Amount. The portion of the Federal Settlement Amount allocable to the state of New York is \$4,747,165.07.
- D. The state of New York shall be entitled to disbursement of its Individual State Settlement Amount from the escrow account ten days after the Escrow Agent has received fully executed state settlement agreements from all of the Participating States. Any escrowed funds not disbursed within 200 days after the Escrow Agent has received the State Settlement Amount shall be disbursed to TAP.
- E. If TAP's agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(e)(1)(C) in the Criminal Action described in Preamble Paragraph B is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the state of New York or TAP. If either the state of New York or

not disbursed within 200 days after the Escrow Agent has received the State Settlement Amount shall be disbursed to TAP.

- E. If TAP's agreed upon guilty plea pursuant to Fed. R. Crim. P. 11(e)(1)(C) in the Criminal Action described in Preamble Paragraph B is not accepted by the Court or the Court does not impose the agreed upon sentence for whatever reason, this Agreement shall be null and void at the option of either the state of New York or TAP. If either the state of New York or TAP exercises this option, which option shall be exercised by notifying all Parties, through counsel, in writing within four business days of the Court's decision, the Parties will not object and this Agreement will be rescinded. If this Agreement is rescinded, TAP waives any affirmative defense based in whole or in part on the statute of limitations for the period of time between April 17, 2001, and thirty days after recission of this Agreement.
- 2. In consideration of this Agreement and payment set forth herein and subject to the exceptions from release set forth in Paragraph 3 below, the state of New York on behalf of itself, its officers, agents, agencies and departments shall release and forever discharge TAP, its predecessors, subsidiaries, joint venture owners, and their corporate parents and affiliates, successors and assigns, and their current and former directors, officers, and employees from any civil or administrative claims for damages or penalties that the state of New York has or may have relating to the Covered Conduct as defined in Preamble Paragraph F. The payment of the Settlement Amount fully discharges TAP from any obligation to pay Medicaid-related restitution, damages, and/or any fine or penalty to the State for the Covered Conduct.
- 3. Notwithstanding any term of this Agreement, the state of New York specifically does not herein release TAP, its predecessors, subsidiaries, joint venture owners, and their corporate

parents and affiliates, successors and assigns, and their current and former directors, officers, and employees from any and all of the following: (a) any potential criminal, civil or administrative claims arising under state of New York revenue codes; (b) any criminal liability not specifically released by this Agreement; (c) any potential liability to the state of New York for any conduct other than the Covered Conduct; (d) any claims based upon obligations created by this Agreement; (e) any reporting of AWP for Lupron to First Data Bank or any other national reporting service for use in Medicaid reimbursement submitted subsequent to the effective date of this agreement; (f) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs; (g) any express or implied warranty claims or other claims for defective or deficient products and services provided by TAP; (h) any claims for personal physical injury or property damage or for other consequential damages arising from the Covered Conduct; (i) any claim based on a failure to deliver items or services due; or (i) any civil or administrative claims against individuals, including current and former directors, officers, and employees of TAP, its predecessors, subsidiaries, joint venture owners, and their corporate affiliates, who receive written notification that they are the target of a criminal investigation, are criminally indicted or charged, or are convicted, or who enter into a criminal plea agreement related to the Covered Conduct.

4. In consideration of the obligations of TAP set forth in this Agreement, conditioned upon TAP's payment in full of the Settlement Amount and except as reserved in paragraph 3 above, the state of New York agrees to release and refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusions from the state of New York's Medicaid program against TAP, its predecessors, subsidiaries, joint venture owners, their

corporate parents and affiliates, successors and assigns, for the Covered Conduct or for TAP's conviction in the Criminal Action. Nothing in this Agreement precludes the state of New York from taking action against TAP in the event that TAP is excluded by the federal government, or for conduct and practices other than the Covered Conduct or the conviction in the Criminal Action. The Medicaid Fraud Control Unit for the state of New York further agrees to refrain from recommending, causing or attempting to cause any administrative action or sanction, including debarment, by any other government agency of the state of New York for the Covered Conduct or for the conviction in the Criminal Action. TAP acknowledges that the state of New York does not have the authority to release TAP from any claims or actions which may be asserted by private payors or insurers, including those that are paid on a capitated basis for providing health care to the States' Medicaid programs.

- 5. This Agreement is expressly conditioned upon resolution of the Criminal Action. In consideration of the Criminal Action, the state of New York agrees that it shall not investigate, prosecute, or refer for prosecution or investigation to any agency, TAP, its predecessors, subsidiaries, joint venture owners, and their corporate parents and affiliates, successors and assigns for the Covered Conduct.
- 6. TAP fully and finally releases the state of New York, its agencies, employees, servants, and agents from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which TAP has asserted, could have asserted, or may assert in the future against the state of New York, its agencies, employees, servants, and agents, related to or arising from the investigation and prosecution of the Covered Conduct up to the effective date of this Settlement Agreement.